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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,923	05/19/2006	Dominique Marechal	065691-0438	5433
22428 7590 08/07/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
TATE, CHRISTOPHER ROBIN				
ART UNIT		PAPER NUMBER		
1655				
MAIL DATE		DELIVERY MODE		
08/07/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,923

Applicant(s)

MARECHAL ET AL.

Examiner

Christopher R. Tate

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30, 31 and 33-60 is/are pending in the application.
- 4a) Of the above claim(s) 54-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30, 31, and 33-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed 14 May 2008 is acknowledged and has been entered. Claims 30, 31, and 33-53 have been examined on the merits (claims 54-60 remain withdrawn for the reasons of record). The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 30, 31, and 33-53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Debregeas et al. (US 2004/0081691) in view of O'Hara et al. (Arch. Family Med., 1998) for the reasons set forth in the previous Office action.

Applicant argues that Debregeas et al. does not teach an intermediate water-repellent layer between the active *Ginkgo biloba* layer and the polymeric layer, and that O'Hara et al. do not cure this deficiency of the Debregeas et al. teachings. However, Debregeas et al. disclose that in the case of a fluid extract, the active plant extract layer (e.g., a fluid *Ginkgo biloba* extract) may be coated with a layer obtained by spraying a solution of a binder such as PVP (see, e.g., paragraphs [0024] and [0041] - which would occur prior to adding the outer layer thereto and, thus, the binder layer (e.g., comprising water-repellent PVP) reasonably reads upon a water-repellent intermediate layer. In addition, Debregeas et al. teach that the granules of the invention containing a layer of plant substance mounted on a neutral core may be coated with an outer layer so as to modify their properties, whereby the outer layer comprises, for example, an enteric polymer, a polymer intended to prolong the release of the plant substance, or a polymer intended to mask the taste or odor of the plant substance {see, e.g. paragraph [0012]}. As such, it would have been obvious to one of ordinary skill in the pharmaceutical art to prepare such granules

using two or more of these coatings (e.g., in sequential order) as each are commonly employed in the pharmaceutical art for their known individual modifying benefits including with respect to providing stability, long-term sustained effectiveness, and/or taste or odor-masking qualities thereto. Debregeas et al. also teach that the granules according to their invention are prepared according to coating techniques known in the art {see, e.g. paragraph [0024]}. Such double coatings including with respect to sustained release granules having an intermediate water-repellant layer (such as those instantly claimed) as well as an outer sustained release polymeric layer (such as those instantly claimed) are notoriously well known and practiced in the pharmaceutical art. Accordingly, the adjustment of these and other types of particular conventional working conditions (e.g., determining result-effective amounts thereof in preparing such granules) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Applicant further argue that it would be expected that such an intermediate water-repellent layer between the active *Ginkgo biloba* layer and the outer coating would interfere with the release of flavone glycosides and, that, unexpectedly, the experimental results in Example 1 of the instant specification show that the sustained release of the flavone glycosides was not affected by this additional intermediate water-repellent layer. However, such an intermediate water-repellent layer would not be expected by one of skill in the pharmaceutical arts to cause any noticeable interference in the *in vivo* release of active ingredients within such granules, including due to the normal digestive process of animals such as humans (e.g., gastric juices, digestive enzymes, etc. within the gastrointestinal tract) which would effectively break down the intermediate layer and, thus, easily release the active ingredients therefrom.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The examiner assigned to this Application has changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655